

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
<b>THIS DOCUMENT RELATES TO:  WAVE 4 CASES ON MOTION EXHIBIT A</b>	

**RESPONSE OF DEFENDANTS TO PLAINTIFFS' MOTION TO EXCLUDE  
THE OPINIONS AND TESTIMONY OF MICHAEL FIEGEN, M.D.  
AND PLAINTIFFS' SUPPORTING MEMORANDUM [ECF NOS. 3673, 3676]**

***INTRODUCTION AND SUMMARY***

Dr. Michael Fiegen, M.D., is a board-certified urogynecologist with over 30 years of experience performing pelvic surgery. Over the past 16 years, he has implanted approximately 2,400 polypropylene midurethral slings, including TVT and TVT-O. Plaintiffs challenge several of Dr. Fiegen's opinions as being beyond the scope of his qualifications or unreliable. However, all of the opinions that Dr. Fiegen intends to offer at trial are well within the scope of his expertise and based on reliable methodology, including his own extensive experience and his review of peer-reviewed literature. For these reasons, Plaintiffs' Motion should be denied.

Dr. Fiegen is a practicing OB/GYN from South Dakota. Mot. Ex. B, Fiegen General Report [ECF No. 3676-2] at 1. In 2013, he received his board-certification in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery, also known as urogynecology. *Id.* at 1–2. He has been involved in six different research projects, including a project investigating the use of stem cells to correct stress urinary incontinence. *Id.* at 2. He has performed pelvic surgery

throughout his 30+-year career and has placed approximately 2,400 polypropylene midurethral slings, including TVT and TVT-O. *Id.* Based on his professional training, education, experience, discussions with other physicians, and review of literature, Dr. Fiegen opines that the TVT and TVT-O are safe and effective for the treatment of stress urinary incontinence. *Id.* at 22–23.

Plaintiffs’ Motion seeks to preclude Dr. Fiegen from testifying about the following: (1) opinions concerning the adequacy of the Instructions for Use (IFU) for TVT and TVT-O; (2) opinions and statements concerning Dr. Fiegen’s personal experience with TVT and TVT-O; and (3) “design opinions.” Plaintiffs’ Motion should be denied in its entirety.

### ***ARGUMENT***

#### **I. Dr. Fiegen Will Not Offer Opinions Concerning the Adequacy of the Warnings, but His Opinions Concerning the Knowledge of the Medical Community Is Reliable and Admissible.**

Plaintiffs devote several pages attacking Dr. Fiegen’s opinions concerning the adequacy of the warnings for TVT and TVT-O. To the extent Plaintiffs’ motion is directed at legal or regulatory opinions concerning the adequacy of the warnings for those products, Dr. Fiegen will not offer such opinions at trial and the Court should deny Plaintiffs’ Motion as moot.

However, to the extent Plaintiffs’ Motion could be construed as attacking Dr. Fiegen’s opinions concerning the common knowledge of the medical community concerning the risks of TVT and TVT-O, the Motion should be denied on its merits. Dr. Fiegen is a board-certified urogynecologist and OB/GYN who has more than 30 years of experience performing pelvic surgeries. Mot. Ex. B, Fiegen General Report at 1–2. He has performed approximately 2,400 midurethral sling procedures. *Id.* at 2. From his training, education, and experience alone, he is qualified to opine about the knowledge of the medical community concerning the risks and benefits of TVT, TVT-O, and other pelvic surgeries. In addition, as discussed throughout his report, Dr. Fiegen has extensively reviewed the scientific literature concerning the safety and

efficacy of TVT, TVT-O, and other SUI procedures. *See generally id.* Based on his professional training, education, and experience, Dr. Fiegen has the requisite expertise to review this literature and ascertain the state of medical knowledge among those surgeons who perform this type of surgery over time.

Through his education, training, experience, and review of literature, Dr. Fiegen is more than qualified to offer opinions concerning the knowledge of the medical community with respect to the risks of TVT, TVT-O, and pelvic floor surgeries in general, and these opinions are reliably supported by the medical literature. Further, this is a proper subject of expert opinion. *See, e.g., Kowalski v. Ethicon, Inc. (In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.)*, No. 2:12-cv-01323, 2017 WL 1128638, at \*2 (S.D. W. Va. Mar. 24, 2017) (noting that “[e]xpert witnesses may properly offer opinions on” “the knowledge of the medical community in general”).

For these reasons, Plaintiffs’ Motion should be denied to the extent it seeks to exclude Dr. Fiegen’s opinions concerning the knowledge of the medical community with respect to the safety and efficacy of TVT, TVT-O, and other surgical procedures for the treatment of SUI.

## **II. Dr. Fiegen’s Opinions About His Personal Experiences Are Reliable and Admissible.**

Plaintiffs seek to preclude Dr. Fiegen “from testifying about his perceived safety and efficacy rates with the subject products from his own practice.” Pls.’ Mem. at 6. Plaintiffs attack such opinions as unreliable on the grounds that patients can have long-term complications and that patients who suffer from such long-term complications often do not return to the implanting surgeon. *Id.* However, Dr. Fiegen’s opinions concerning his personal experiences and results with TVT and TVT-O are reliable and the proper subject of expert opinion.

In previous cases, this Court has consistently allowed practicing medical doctors to offer opinions and testimony concerning their general personal experiences with mesh products. *See, e.g., Trevino v. Boston Sci. Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at \*33 (allowing expert urogynecologist to offer opinions on safety and experience based on general experience with his patients). Where the Court has drawn the line and excluded testimony is when a physician seeks to offer “precise statistics” based on the doctor’s personal practice. *In re Ethicon, Inc.*, MDL No. 2327, 2016 WL 4542054, at \*4 (S.D. W. Va. Aug. 30, 2016). This Court has held that “expert testimony about specific rates is unreliable without more than the expert’s assurances of reliability.” *Id.*

Dr. Fiegen is not offering any opinions concerning exact statistics or complication rates calculated from his medical practice. Nowhere in his report does Dr. Fiegen provide success rates, complication rates, or other exact statistics among the patients that he has treated in his medical practice. Instead, he is offering opinions and testimony concerning his general personal experience with TVT and TVT-O. These personal experiences provide further support for and bolster Dr. Fiegen’s opinions concerning the safety and efficacy of TVT and TVT-O. This is precisely the same kind of opinions and testimony this Court has allowed expert physicians to offer in previous cases, and Plaintiffs have not presented any reason to depart from these prior rulings. Accordingly, Plaintiffs’ Motion on this point should be denied.

### **III. Dr. Fiegen’s Opinions on Safety and Efficacy Are Reliable and Within the Scope of His Qualifications.**

Plaintiffs move to exclude any opinions from Dr. Fiegen concerning the “design” of TVT and TVT-O. Pls.’ Mem. at 9–14. Plaintiffs claim that, because Dr. Fiegen is not a “design” expert and lacks certain knowledge, he cannot offer any “opinion about the design or safety of the subject devices.” *Id.* at 14. However, the actual opinions disclosed in Dr. Fiegen’s reports are

not “design” opinions; rather, these are reliable opinions on safety and efficacy that are squarely within the scope of Dr. Fiegen’s qualifications.

This Court has explained that simply because an expert uses the word “design,” he does not need to be a “design expert.” *See, e.g., In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 988946, at \*3 (S.D. W. Va. Mar. 10, 2017). “[T]he mere utterance of a single word is not some incantation that transforms an opinion about one thing into something else.” *Id.* This Court has clarified that a “design opinion” is an opinion dealing with the design process, such as “opinions about pre-marketing product testing and product development.” *Id.* Dr. Fiegen does not and will not offer any opinions about the process of designing mesh implants. Thus, Plaintiffs’ Motion should be denied as moot to the extent it seeks to exclude true “design” opinions.

Plaintiffs’ “design” argument appears to be directed at Dr. Fiegen’s opinion that the TVT and TVT-O are safe and effective. Plaintiffs’ Motion on this point is without merit. As an experienced board-certified urogynecologist who has performed over 2,000 sling procedures, Dr. Fiegen is more than qualified to offer opinions about the safety and efficacy of incontinence procedures and implants, including TVT and TVT-O. As noted above, Dr. Fiegen has extensive personal experience with these procedures and has reviewed numerous peer-reviewed publications concerning the safety and efficacy of these and other similar procedures.

Dr. Fiegen’s specialized knowledge, training, education, experience, and literature review enable him to compare the synthetic midurethral slings to procedures that do not use mesh and form reliable opinions concerning the relative safety and efficacy of Ethicon’s products. *See, e.g., In re Ethicon, Inc.*, MDL No. 2327, 2016 WL 4493666, at \*3 (S.D. W. Va. Aug. 25, 2016) (finding that urogynecologist’s “extensive clinical and research experience qualifies [him] to

opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products"); *Carlson v. Boston Sci. Corp.*, No. 2:13-cv-05475, 2015 WL 1931311, at \*35–36 (S.D. W. Va. Apr. 28, 2015) (finding urogynecologist's opinions on safety and efficacy of mesh product based on literature review and personal experience were reliable). As such, his opinions about these subjects will clearly assist the trier of fact to understand the evidence or determine facts at issue in the proceedings and thus are admissible under Federal Rules of Evidence 702 and 703.

Plaintiffs' "design" argument also criticizes Dr. Fiegen for perceived inconsistencies in his opinions on curling, lack of knowledge of certain internal Ethicon documents and events, and lack of knowledge as to the preparation of his reliance list. Pls.' Mot. at 9–10. These criticisms do not undermine the reliability of Dr. Fiegen's safety and efficacy opinions, which are based on peer-reviewed literature, in addition to Dr. Fiegen's personal experience.

With respect to Dr. Fiegen's opinions on curling, his deposition testimony does not conflict with his opinions in his report. Dr. Fiegen states in his report:

If the TVT and TVT-O meshes are implanted according to the IFU and Ethicon's training materials, roping, curling, and fraying, is not an issue. The peer-reviewed published medical literature regarding the slings does not discuss these issues, and I have not seen any clinically significant roping, curling, or fraying in my practice.

Mot. Ex. B, Fiegen General Report at 20. At his deposition, Dr. Fiegen unequivocally testified, consistent with his report, that he had never seen literature regarding the roping, curling, or fraying of TVT and TVT-O:

Q. And then you continue on, "The peer-reviewed published medical literature regarding the slings does not discuss these issues."

And when you write that sentence, "these issues," you're referring to the TVT and TVT-O mesh is roping, curling, and fraying; correct?

A. Yes.

Q. Are you aware of any peer-reviewed published medical literature regarding slings that discusses roping, curling, and fraying of the TVT and TVT-O meshes?

A. **I'm sorry. If it does exist, I'm not familiar with it.**

Mot. Ex. C, Fiegen 3/17/17 Dep. Tr. 56:23–57:10. Unlike his report, the testimony that Plaintiffs cite in their Motion was not limited to TVT or TVT-O; instead, it covered all transvaginal SUI meshes. *See* Pls.' Mem. at 10 (citing Mot. Ex. C, Fiegen 3/17/17 Dep. Tr. 26:9–13). Thus, there is no inconsistency between his testimony and the opinions actually expressed in his report.

As for any perceived complaints with Dr. Fiegen's lack of familiarity with his reliance list, this issue is irrelevant. Throughout his report, Dr. Fiegen provides specific citations to literature and other documents that support his opinions. *See generally* Mot. Ex. B, Fiegen General Report. The inclusion of extraneous materials in Dr. Fiegen's reliance list is therefore harmless, at best, and does not impact the reliability or admissibility of his opinions.

Plaintiffs' remaining critiques concerning which internal Ethicon documents Dr. Fiegen reviewed or did not review go to the weight of his testimony, not its admissibility. *See, e.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D. W. Va. 2014) (finding that failure to review certain internal Ethicon documents did not render expert urogynecologist's opinions unreliable because his "failure to review particular documents goes to the weight of his opinion, not its admissibility").

For these reasons, the Court should deny Plaintiffs' Motion with respect to opinions concerning the safety and efficacy of TVT and TVT-O.

Respectfully submitted,

/s/ Philip J. Combs

Philip J. Combs (W.Va. Bar #6056)  
Thomas Combs & Spann PLLC  
300 Summers Street  
Suite 1380 (25301)  
P.O. Box 3824  
Charleston, WV 25338  
(304) 414-1807  
pcombs@tcspllc.com

/s/ Christy D. Jones

Christy D. Jones  
Butler Snow LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010  
(601) 985-4523  
christy.jones@butlersnow.com

COUNSEL FOR DEFENDANTS  
ETHICON, INC. AND JOHNSON & JOHNSON



**CERTIFICATE OF SERVICE**

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Philip J. Combs  
Philip J. Combs